MAR 9 2006

510(k) Summary for the
Dimension® Iron Calibrator
(IRON Cal – DC 85)

A. 510(k) Number: k060266

B. Analyte: Iron Calibrator

C. Type of Test: Calibrator Material

D. Applicant:
Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager
(302) 631-9454

Date of Preparation: January 30, 2006

E. Proprietary and Established Names:
Dimension® Iron Calibrator (IRON Calibrator- DC 85)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – CALIBRATOR

2. Classification: Class II

3. Product Code: JIS - CALIBRATORS, PRIMARY

4. Panel: CLINICAL CHEMISTRY

G. Intended Use:
1. Intended use(s):
The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for the Dimension® clinical chemistry system.

2. Indication(s) for use:
The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for the Dimension® clinical chemistry system.

This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. Device Description:

The IRON calibrator is an aqueous solution of iron wire dissolved in a dilute solution of HCl. The kit consists of 6 ampules, two at each of three levels.

. Substantial Equivalence Information:

1. Predicate Device: Dimension® IRN/TIBC Calibrator (DC21)

2. Predicate K Number(s): K944093

3. Comparison with Predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	To calibrate the iron method for the Dimension® clinical chemistry system.	same
Traceability	NIST SRM 937 (NIST SRM: National Institute of Standards and Technology- Standard Reference Material)	
Matrix	Aqueous solution of iron wire dissolved in a dilute solution of HCl	same
Number of Levels	3	same

Differences		
Item	**Device**	**Predicate**
Target Concentrations	0, 50, 1075 ug/dL	50, 500 1000ug/dL

J. Standard/Guidance Document Referenced:

1. Guidance;
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards;

GP22-A	Continuous Quality Improvement Essential Management Approaches
CEN 13640	Stability testing of In-Vitro Diagnostic Devices

ISO 14971:2000	Medical devices -Application of risk management to medical devices
ISO 15223	Medical devices – Symbols to be used with medical device labeling and information to be supplied

K. Test Principle:

The Dimension® Iron Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension® IRON (Cat # DF85) method for the Dimension® clinical chemistry system.

L. Performance Characteristics:

1. Stability

Target shelf life for the Dimension® IRON Calibrator is 12 months. Studies require 13 months of real time testing on three lots of product. Calibrator shelf life is determined by comparing results of the product stored at 4°C with product stored at -20°C to ensure that analytical system drift is dissociated with calibrator drift.

2. Traceability:

The assigned values of the IRON calibrator are standardized to NIST SRM 937 (NIST SRM: National Institute of Standards and Technology- Standard Reference Material). Six working Iron Standard Solutions of NIST SRM 937 (0, 25, 50, 75, 500, 1075 µg/dL) are prepared and used to assign each new lot of calibrator.

3. Value Assignment

The new calibrator levels are made by adding acid dissolved NIST 837 into base matrix. The new calibrator lots are assigned verses the six working standard solutions prepared from NIST SRM 937(Reference Lot). The new calibrator lot must have acceptable recovery verses the Reference Lot and a Control Calibrator Lot (Control Calibrator Lot = Any Approved Calibrator Lot).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Andrea M. Tasker
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Glasgow Business Community
P.O. Box 6101, Building 500, M/S 514
Newark, DE 19714-6101

Re: k060266
Trade/Device Name: Dimension® IRON Calibrator (IRON Cal- DC85)
Regulation Number: 21 CFR§ 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: January 30, 2006
Received: February 1, 2006

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K060266

Device Name:

Dimension® IRON Calibrator (IRON Cal- DC85)

Indications for Use:

The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for the Dimension® clinical chemistry system.

Prescription Use ✓ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060266